Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of the effects of oral trehalose supplementation on glycemic control in patients with type 2 diabetes

Protocol summary

Study aim

The aim of this study is to determine the effectiveness of trehalose on reducing glycemic indices in patients with diabetes type2

Design

This study has been designed as a randomized, ،triple-blind, placebo-controlled and parallel trial.

Settings and conduct

A total of 40 enrolled patients will be divided into two treatment and control groups (trehalose and sucrose). Patients will be instructed to ingest the preparation (1.65 g twice a day), approximately 3.3 g/day for 3 months (trehalose n=20, placebo n=20). The participants were permitted to prepare the substances for consumption in a variety of ways, such as dissolving them in beverages. Ghaem Hospital/ Faculty of Medicine/ Faculty of pharmacy

Participants/Inclusion and exclusion criteria

Inclusion criteria: 40 patients (male or female) with non-insulin-dependent diabetes (HbA1C 7-9%) having stable condition Exclusion Criteria: Patients with any type of insulin-dependent diabetes receiving insulin therapy (also patients participating will be excluded from the study if they need insulin) Patients with renal dysfunction (eGFR less than 30 ml/min) Patients with severe liver dysfunction or cirrhosis. Patients regularly receiving oral or injectable corticosteroids or those who used α-Glucosidase Inhibitors such as acarbose. Patients who were pregnant or nursing or wished to conceive.

Intervention groups

Patients will be randomly divided into two treatment and control groups, which will be received trehalose and sucrose as intervention/placebo groups, respectively. Enrolled patients will be instructed to ingest the preparation in opaque sachet form (1.65 g twice a day) for 3 months (trehalose n=20, placebo n=20).

Main outcome variables

The primary endpoint: changes in HOMA-IR as an index of insulin resistance. Secondary endpoints include changes in fasting plasma glucose (FPG), insulin, HbA1c, C-peptide and hs-CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130829014521N18**
Registration date: **2021-03-16, 1399/12/26**
Registration timing: **prospective**

Last update: **2021-03-16, 1399/12/26**
Update count: **0**

Registration date

2021-03-16, 1399/12/26

Registrant information

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Name of organization / entity
Mashhad University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effects of oral trehalose supplementation on glycemic control in patients with type 2 diabetes

Public title

Trehalose and diabetes type 2

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male or female patients aged between 35 and 85 years Patients with non-insulin-dependent diabetes mellitus in a stable condition.

Exclusion criteria:

Patients with type 1, type 2, or secondary diabetes receiving insulin therapy. Patients with renal dysfunction (eGFR less than 30 ml/min). Patients with severe liver dysfunction or cirrhosis. Patients regularly receiving oral or injectable corticosteroids. Patients who were pregnant or nursing or wished to conceive. Patients participating in this study will be excluded from the study if they need insulin. Patients who used α-Glucosidase Inhibitors such as acarbose will be excluded from the study.

Age

From **35 years** old to **85 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

This study has been designed as a randomized, triple-blind, placebo-controlled and parallel trial. Simple randomization for allocation and sealed envelope approach would be considered for concealed allocation.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study has been designed as triple-blind and persons including participants, care providers, investigators, and outcome assessors, keeping unaware of the treatment administered, moreover, drug and placebo vials have similar packaging and labeling.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of National institute for medical research development

Street address

No. 21, west Fatemi Ave, Besat Ave, Tehran

City

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Tehran

Postal code

1419693111

Approval date

2020-11-18, 1399/08/28

Ethics committee reference number

IR.NIMAD.REC.1399.267

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11. 9

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

HOMA-IR alterations

Timepoint

At the beginning and end of the intervention trial (Day 0 and week 12)

Method of measurement

HOMA-IR = fasting insulin (microU/L) x fasting glucose (nmol/L)/22.5

Secondary outcomes

1

Description

fasting plasma glucose (FPG)

Timepoint

Baseline and week 12

Method of measurement

Enzymatic assay

2

Description
Fasting insulin
Timepoint
Baseline and week 12
Method of measurement
Immunoassay

3

Description
HbA1c
Timepoint
Baseline and week 12
Method of measurement
chromatography

4

Description
C peptide
Timepoint
Baseline and week 12
Method of measurement
Immunoassay

5

Description
hs-CRP
Timepoint
Baseline and week 12
Method of measurement
Turbidimetric

Intervention groups

1

Description
Intervention group: Terhalose (natural disaccharide), 1.65 g twice a day (3.3 g/day) for 3 months, in opaque sachet form
Category
Treatment - Drugs

2

Description
Control group: Sucrose, 1.65 g twice a day (3.3 g/day) for 3 months, in opaque sachet form
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Mohammad Ali Yaghoubi
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Ahmadabad Blvd, Mashhad, Khorasan Razavi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
National Institute for Medical Research Development
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available